From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Tuesday, October 09, 2012 11:28 PM
To: Marshall Allen
Subject: RE: Compounding pharmacy story

Hi Marshall,

Still combing through emails for the day. Sorry for the delay. Here is some background information on our authorities re: compounding pharmacies.

The state boards of pharmacy that license pharmacies and pharmacists oversee their day-to- day operations. FDA also has some authority over drugs made by compounding pharmacies. The agency can initiate enforcement action against a compounded drug if it is adulterated or misbranded in certain ways (e.g., if the drug is contaminated or falsely labeled). But the law exempts some pharmacy compounding from certain requirements that are otherwise applicable to drugs manufactured for the United States. For example, compounded drugs are not approved by the FDA and therefore do not undergo premarket review for safety and effectiveness.

When the Agency becomes aware of potentially contaminated or otherwise adulterated or misbranded compounded drug products, FDA investigates and works with its state counterparts to take appropriate action as quickly as possible.

Section 503A (21 U.S.C. § 353a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) describes the circumstances under which drugs compounded by physicians and pharmacists are exempt from several statutory requirements, which include a premarket review for safety and effectiveness. There are two conflicting decisions from federal appellate courts on whether section 503A is valid and enforceable by FDA. The Agency also has a compliance policy guide describing the agency's policy on pharmacy compounding.

See:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm134919.htm

See:
http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM118050.pdf

Please let me know if you have any additional questions.
Erica

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From: Marshall Allen [mailto:Marshall.Allen@propublica.org]

Sent: Tuesday, October 09, 2012 1:36 PM
To: Clark-Lynn, Sarah
Subject: Compounding pharmacy story
Hi Sarah, I'd like to speak with someone from the FDA ASAP today for a story I'm writing about the regulation of compounding pharmacies.

I'm on a tight deadline so I hope to hear back soon.

Marshall

Marshall Allen
Staff reporter, ProPublica
917.239.8722 (cell)
917.512.0214 (desk)